

**I. Listing of the Claims**

This listing of the claims is being provided for the convenience of the Examiner.  
No amendments to the claims have been made.

1. (Previously Presented) A solid, oral, controlled release pharmaceutical dosage form comprising a pharmaceutically active ingredient having a solubility in water of greater than 1gm in 250ml water at 25°C, dispersed in a matrix, wherein the matrix comprises a mixture of a hydrophobic fusible material having a melting point of greater than 40°C and a hydrophilic, organic, polymeric fusible wicking agent, wherein the weight ratio of hydrophobic fusible material to hydrophilic, organic polymeric wicking agent in said mixture is in the range from about 8:1 to about 16:1, wherein the dosage form provides, as tested by the Ph. Eur. Basket method at 100 rpm 900 ml aqueous buffer (pH 6.5) containing 0.05% w/w Polysorbate 80 at 37°C, an essentially zero order rate of release of the pharmaceutically active ingredient over a period of 8 hours, the amount of pharmaceutically active ingredient released over eight hours being in the range of 15% to 45%, and when tested in a group of at least five healthy humans the median t<sub>max</sub>, based on blood sampling at half hourly intervals, is in the range of from about 2.5 to about 6 hours, and the ratio of mean C<sub>max</sub> to the mean plasma level at 24 hours is in the range of about 1.5 to about 3.5.

2. (Original) A pharmaceutical dosage form according to claim 1, wherein the median t<sub>max</sub> is in a range from 2.5 to 3.5 hours.

3. (Previously presented) A pharmaceutical dosage form according to claim 1, which has a W<sub>50</sub> in the range from about 15 to about 35 hours when tested *in vivo* as set forth in claim 1.

4-5. (Cancelled)

6. (Previously presented) A pharmaceutical dosage form according to claim 1, in which the pharmaceutically active ingredient is morphine, a pharmaceutically acceptable salt thereof or mixtures thereof.
7. (Previously Presented) A pharmaceutical dosage form according to claim 1, which is suitable for once a day dosing.
8. (Previously presented) A pharmaceutical dosage form according to claim 1, in the form of a tablet or a capsule containing multiparticulates.
- 9-10. (Cancelled)
11. (Previously Presented) A solid, oral controlled release pharmaceutical dosage form which comprises a pharmaceutically active ingredient having a solubility in water of greater than 1gm in 250ml water at 25°C dispersed in a matrix, wherein the matrix comprises a mixture of a hydrophobic fusible material having a melting point of greater than 40°C and a hydrophilic, organic, polymeric fusible wicking agent, wherein the weight ratio of hydrophobic fusible material to hydrophilic, organic polymeric wicking agent in said mixture is in the range from about 8:1 to about 16:1, the dosage form being obtainable by a process comprising:
  - (a) mechanically working in a high shear mixer a mixture of hydrophobic, fusible binder and an organic, fusible, polymeric material which in the finished dosage form is capable of functioning as a wicking agent at a speed and temperature at which the binder melts or softens and the mixture forms agglomerates;
  - (b) extruding the agglomerates whereby the extrudate is obtained as extruded pieces or an elongate extrudate is formed into pieces;
  - (c) continuing mechanically working the pieces in a high shear mixer; and

(d) continuing mechanically working with additional binder material at a temperature and speed at which the additional binder melts or softens.

12. (Previously presented) A pharmaceutical dosage form according to claim 1, which has a  $W_{50}$  in the range from about 20 to about 30 hours when tested *in vivo* as set forth in claim 1.

13. (Previously presented) A pharmaceutical dosage form according to claim 1, in which the pharmaceutically active ingredient is morphine sulfate or morphine hydrochloride.

14. (Previously Presented) A pharmaceutical dosage form according to claim 1, wherein the median  $t_{max}$  is in the range from about 2.5 to about 3.5 hours.

15. (Previously Presented) A pharmaceutical dosage form according to claim 1, wherein the  $W_{50}$  is in a range from about 15 to about 35 hours.

16. (Previously Presented) A pharmaceutical dosage form according to claim 1, wherein the  $W_{50}$  is in a range from about 20 to about 30 hours.

17. (Cancelled)

18. (Previously Presented) A pharmaceutical dosage form according to claim 1, wherein the pharmaceutically active ingredient is morphine, a pharmaceutically acceptable salt thereof or mixture thereof.

19. (Previously Presented) A pharmaceutical dosage form according to claim 1, wherein the pharmaceutically active ingredient is morphine sulfate or morphine hydrochloride.

20. (Previously Presented) A pharmaceutical dosage form according to claim 1, wherein the pharmaceutically active ingredient is morphine, a pharmaceutically acceptable salt thereof or mixture thereof.
21. (Previously Presented) A pharmaceutical dosage form according to claim 1, wherein the pharmaceutically active ingredient is morphine sulfate or morphine hydrochloride.
22. (Previously presented) A pharmaceutical dosage form according to claim 1, which is suitable for once a day dosing.
23. (Cancelled)
24. (Previously Presented) A pharmaceutical dosage form according to claim 1, in the form of a tablet or capsule containing multiparticulates.
25. (Previously Presented) A pharmaceutical dosage form according to claim 1, in the form of a tablet or capsule containing multiparticulates.